

DICKSON-DIVELEY MIDWEST ORTHOPAEDIC CLINIC, INC.

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 97N-484S

Dear Sir or Madam:

I am^{an} orthopaedic spine surgeon in Kansas City, Missouri, and have been in practice over ten years. It has come to my attention that the FDA is considering a change in its pre-market requirements of allograft tissues. I think this would lead to a tremendous problem. Allograft tissues have been used extensively to treat our patients. Heart transplants, kidney transplants, cornea transplants, all would be affected by a change in the requirements. In orthopaedics, we do use bone in many instances) in fractures at high risk for non-union, or where bony defects are huge, allograft is often very helpful in providing a scaffold for bone formation. Iliac crest allograft is very useful in performing anterior cervical fusions and prevents the need for making a separate; painful incision over one's iliac crest to obtain autograft and has a high rate of success and use. Use of allograft in performing anterior lumbar fusions also has a long track record.

It is my opinion that companies which have manufactured implants are jealous of companies which bring to market allograft products. There are significant differences between an implant and allograft. Allograft is completely resorbable and can be remodeled and incorporated by the body.

I urge you to not turn back the calendar on the progress we have made in using all kinds of allograft tissues by changing the FDA's pre-market requirements. It would prevent us from helping our patients to our best abilities.

If you have any questions or comments, do not hesitate to call or write me.

Sincerely,



Mark Bernhardt, M.D.
Clinical Associate Professor
University of Missouri-Kansas City School of Medicine

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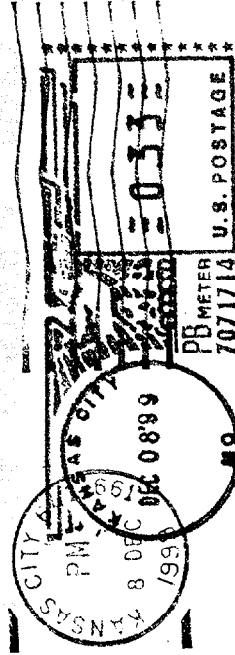
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